

### ***Remarks***

#### ***I. Support for Amendments and Status of the Claims***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 220-262, 265-272, 275-280, 283-285, 292-297, 300-306, 309-316, 319, 320, 329-332, 335-465 are pending in the application, with claims 220, 359, 362 and 463 being the independent claims. Claims 263, 264, 273, 274, 281, 282, 286-291, 298, 299, 307, 308, 317, 318, 321-328, 333 and 334 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 1-219 were previously cancelled. Claims 230-237, 245-247, 250-257, 259-262, 265-267, 277-280, 283-285, 292-297, 300-306, 309-316, 319, 320, 329-331 and 335-354 have been withdrawn. Amendment is sought to claims 220, 221, 239, 245, 258, 262, 272, 280, 297, 306, 316, 332, 356, 358 and 359. New claims 362-465 are sought to be entered.

Amendments to claims 221, 245 and 258 are sought to correctly number the species recited in the Markush groups therein. Accordingly, these amendments do not introduce new matter. The amendment to claim 239 is sought to correct a minor grammatical error. Accordingly, the amendments to claims 221, 239, 245 and 258 do not introduce new matter.

Claim 262 has been amended to incorporate elements from its dependent claims 263 and 264. Likewise, elements from dependent claims 281 and 282 are now incorporated into claim 280; elements from dependent claims 298 and 299 are now incorporated into claim 297; elements from dependent claims 307 and 308 are now incorporated into claim 306; elements from dependent claims 317 and 318 are now incorporated into claim 316; and elements from dependent claims 333 and 334 are now incorporated into claim 332. Accordingly the amendments to claims 262, 272, 280, 297, 306, 316 and 332 do not introduce new matter.

Amendments to claims 220 and 359 are sought to further define the nature of the first attachment site. These amendments are supported by the specification at, *inter alia*, pages 7, 9, 16-17, 27, 29-30, 40, 61 and 87. Amendments to claims 356 and 358 are sought to better conform these claims to USPTO practice, and are supported by the specification at, *inter alia*, pages 3, 4, 7, 8, 15, 18 and 81. Accordingly the amendments to claims 220, 356, 358 and 359 do not introduce new matter.

These amendments to the claims do not introduce new matter, are solely to correct minor errors, to better conform the claims for USPTO practice, and/or to better place them in a condition for immediate allowance. Entry and consideration of these amendments are respectfully requested.

New claims 362-465 are sought to be entered. New claim 362 is identical to previous claim 220, except that it now specifies the antigens or antigenic determinants which were found in dependent claim 258 (and were originally found in claim 35, as filed). New claims 363-401, 403 and 405-465 depend from claim 362 and parallel claims 220-361. New claims 402 and 404 depend from claim 220 and further define the nature of the association between the first and second attachment site. New claims 402 and 404 are supported by the specification at, *inter alia*, pages 7, 9, 16-17, 27, 29-30, 40, 61 and 87.

## ***II. Summary of the Office Action***

In the Office Action dated April 29, 2005, (hereinafter "Office Action") the Examiner has objected to claims 268-276 as being dependent on a rejected base claim. Claims 220-229, 238-244, 248, 249, 258, 329, 332, 333 and 355-361 have been rejected under 35 U.S.C. § 103(a). Applicants respectfully offer the following remarks concerning each of these elements of the Office Action, and request reconsideration of the present application in view of these remarks.

***III. The Examiner's interview summary and status of the withdrawn claims***

In the Office Action at page 1, the Examiner has indicated that claims 230-237, 245-247, 250-257, 259-267, 277-331 and 334-354 are withdrawn. The withdrawn claims listed on page 1 of the Office Action differed from those listed on pages 2-3 of the Office Action. In an August 24, 2005 telephone message to the undersigned the Examiner has indicated that the correct listing of withdrawn claims is that found on page 1. This telephone message was confirmed by an Examiner's Interview Summary, mailed August 26, 2005. Applicants have therefore listed the withdrawn claims according to the listing on page 1 of the Office Action.

On pages 2-3 of the Office Action the Examiner has noted that claims were withdrawn from consideration pursuant to 37 C.F.R. § 142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim. Claims 230-237, 245-247, 250-257, 259-262, 265-267, 277-280, 283-285, 292-297, 300-306, 309-316, 319, 320, 329-331 and 335-354 are presently listed as withdrawn. Upon the identification of allowable subject matter in the generic or linking claim, Applicants respectfully request that the Examiner rejoin and examine claims 230-237, 245-247, 250-257, 259-262, 265-267, 277-280, 283-285, 292-297, 300-306, 309-316, 319, 320, 329-331 and 335-354.

***IV. The objection to claims 268-276***

On page 4 of the Office Action the Examiner has objected to claims 268-276 as being dependent upon a rejected base claim, claim 220. Claims 273 and 274 have been cancelled. Upon allowance of claim 220, Applicants request withdrawal of the objection and allowance of claims 268-272, 275 and 276.

**V.     *The Rejection Under 35 U.S.C. § 103(a)***

In the Office Action at pages 3-4, the Examiner has rejected claims 220-229, 238-244, 248-249, 258, 329, 333, 355-361 under 35 U.S.C. § 103(a) over Mastico *et al.*, U.S. Patent No. 5,698,424 (hereinafter "Mastico") in view of Stanworth *et al.*, WO 90/15878 (hereinafter "Stanworth"). Applicants respectfully traverse this rejection.

However, in order to expedite prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended the claims. None of the present independent claims 220, 359, 362 or 463 are rendered obvious by the cited art and hence their dependent claims are similarly non-obvious. Reconsideration and withdrawal of the rejection is respectfully requested.

***Claim 220 and its dependent claims***

Independent claim 220 is presently drawn to compositions in which at least one self-antigen, a peptide or fragment thereof, is bound via at least one non-peptide bond to a virus-like particle of an RNA bacteriophage through the association of at least one first and at least one second attachment site, wherein *said first attachment site is not a sulfhydryl group*.

In contrast, Mastico does *not* disclose or suggest the presently claimed invention, but is limited to the disclosure of a peptide or an enzyme coupled to the surface of a capsid composed of modified coat proteins of the RNA bacteriophage MS-2, wherein the coat proteins have been modified by removal of the cysteine residues present externally of the N-terminal protruberant  $\beta$ -hairpin of the coat proteins and by insertion of a cysteine residue within the region corresponding to the N-terminal protruberant  $\beta$ -hairpin, and wherein the peptide or the enzyme is coupled to the surface of the capsid *via the sulfhydryl group of a cysteine residue* inserted within the coat protein of MS-2. See Mastico col. 2, lines 8-18.

Therefore, the compositions of present claim 220 differ from those disclosed in Mastico, in particular, in that proteins or peptides of self-antigens in the present compositions are bound to the RNA bacteriophage particle by means that do *not* involve a sulfhydryl group as attachment site on the part of the RNA bacteriophage virus-like particle. Accordingly, Mastico does not disclose the presently claimed invention, as recited in present claim 220. The deficiency in Mastico is not cured by Stanworth. Hence, claim 220 and its dependent claims are not rendered obvious by the cited art. Reconsideration and withdrawal of the rejection is respectfully requested.

***Claim 362 and its dependent claims***

Independent claim 362 is presently drawn to compositions in which at least one self-antigen, a peptide or fragment thereof, which is selected from a *specific* group, is bound via at least one non-peptide bond to a virus-like particle of an RNA bacteriophage.

In contrast, *neither* Mastico *nor* Stanworth disclose or suggest the invention presently claimed in claim 362. Mastico is limited to the disclosure of a limited number of antigens or antigenic determinants coupled to the surface of a capsid composed of modified coat proteins of the RNA bacteriophage MS-2 (*See* Mastico cols. 6 to 8, Examples F and G). Stanworth does not cure the defects of Mastico as it fails to teach or suggest additional species within claim 362. Hence, claim 362 and its dependent claims are also not rendered obvious by art cited against claims 220-361.

***VI. Other Matters***

Applicants note that the Examiner has again acknowledged that the elected combination is free of the art, and that the claims would be allowable if limited to the elected species. Office Action at page 4. Applicants request that the Examiner allow the claims to

the elected species, including the generic linking claims, and thereafter examine and allow claims to the nonelected species that are linked by such allowable linking claims, in accordance with MPEP § 809.04.

### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply, and allowance of all pending claims, are respectfully requested.

Respectfully submitted,

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